

the study was not conducted in compliance with such regulations, a brief statement of the reason for the non-compliance.

[50 FR 7492, Feb. 22, 1985, as amended at 50 16668, Apr. 26, 1985]

§ 171.7 Withdrawal of petition without prejudice.

(a) In some cases the Commissioner will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

(b) At any time before the order provided for in § 171.100(a) has been forwarded to the FEDERAL REGISTER for publication, the petitioner may withdraw the petition without prejudice to a future filing. Upon refiling the time limitation will begin to run anew.

§ 171.8 Threshold of regulation for substances used in food-contact articles.

Substances used in food-contact articles (e.g., food-packaging or food-processing equipment) that migrate or that may be expected to migrate into food at negligible levels may be reviewed under § 170.39 of this chapter. The Food and Drug Administration will exempt substances whose uses it determines meet the criteria in § 170.39 of this chapter from regulation as food additives and, therefore, a food additive petition will not be required for the exempted use.

[60 FR 36596, July 17, 1995]

Subpart B—Administrative Actions on Applications

§ 171.100 Regulation based on petition.

(a) The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time

is extended as provided for in section 409(c)(2) of the Act), a regulation prescribing the conditions under which the food additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity that may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and prior to the forwarding of the order to the FEDERAL REGISTER for publication shall notify the petitioner of such order and the reasons for such action; or by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(b) If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

§ 171.102 Effective date of regulation.

A regulation published in accordance with § 171.100(a) shall become effective upon publication in the FEDERAL REGISTER.

§ 171.110 Procedure for objections and hearings.

Objections and hearings relating to food additive regulations under section 409 (c), (d), or (h) of the Act shall be governed by part 12 of this chapter.

[42 FR 14491, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977]

§ 171.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

(a) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.

(b) Any such petition shall include an assertion of facts, supported by data,